CONICAL, THREADED SUBTALAR IMPLANT

TECHNICAL FIELD

This invention relates generally to biomedical implants and in particular to conical, threaded subtalar implants and methods for manufacturing the same.

BACKGROUND

Pes planus, or pes valgo planus, is a deformity producing a severe flat foot. The deformity occurs largely at one particular joint, the talocalcaneal articulation, which is the joint between the talus and calcaneus bones in the foot. There are typically three separate components of a valgus deformity at this joint: first, the calcaneus has a valgus position; second, the head of the talus angulates downward; and third, the forefoot is totally abducted in relation to the hindfoot. In addition, the Achilles tendon may be pulled laterally due to the outward rotation, or eversion, of the calcaneus.

Pes valgo planus often results from the failure of the arch to form in one or both feet of a child aged two to four, which is the typical age for the natural formation of the arch in the foot. The arch may fail to form due to loose joint connections or baby fat lodged between the foot bones of the child. Pes valgo planus also occurs in adults as a result of Posterior Tibial Tendon Dysfunction (PTTD), one of the more common tendon disorders involving the ankle. The posterior tibial tendon helps support the arch of the foot and provides power to point the foot down and to turn the foot inward. PTTD is typically caused by chronic inflammation, degenerative changes, and occasionally trauma, which lead to stretching, laxity, and eventual rupture of the posterior tibial tendon. People suffering from PTTD often experience tenderness and inflammation along the inner part of the ankle, and may experience weakness when standing on their toes. As the disease progresses, the person may experience loss of the arch of the foot while standing, and the foot tends to turn outward under weight. Late stages of the disease are associated with a flat foot deformity with degenerative changes in the joints below the ankle.

In many cases, the symptoms of pes valgo planus may be treated using conservative measures such as anti-inflammatory medications, rest, ice, shoe inserts or orthotic supports, or even ankle-foot braces. However, in some cases, such measures prove inadequate and the person may continue to experience severe foot or ankle pain or suffer from night cramps, pain when walking and/or standing, or lower back and knee pain. In such cases, a subtalar implant may be used to correct the

flatfoot deformity while maintaining mobility of the subtalar joint. The subtalar implant is a small device that is inserted into a small opening in the talocalcaneal joint called the sinus tarsi. The placement of the implant restores the arch by preventing the displacement of the talus and by preventing the foot from rolling-in (pronating). In some cases, tissue may grow around the implant which helps hold the implant in place within the sinus tarsi.

SUMMARY OF THE INVENTION

The present invention provides a conical, threaded medical implant adapted for implantation within a person's body to limit motion in a joint having excessive mobility. In some embodiments, a medical implant includes a body having a conical portion and adapted for implantation into a person's body. A plurality of threads formed around an exterior surface of the conical portion of the body are adapted to help secure the implant in place within the person's body. In certain embodiments, the medical implant is a subtalar implant adapted for implantation into the person's body and sized to fit within a sinus tarsi of a subtalar joint in the person's body for at least partially preventing displacement of the talus. The plurality of threads may help secure the subtalar implant within the sinus tarsi.

Particular embodiments of the present invention may provide one or more advantages. For example, in certain embodiments in which the medical implant is adapted for use as a subtalar implant, the implant may be inserted via a subtalar arthroereisis operation into the sinus tarsi of a person suffering from pes valgo planus. Once inserted, the implant may reduce calcaneal eversion to a desirable level and block excessive displacement of the talus, thus correcting the pes valgo planus condition. In addition, the implant may allow normal motion of the subtalar joint while correcting the pes valgo planus, thus allowing the person to function normally.

Another advantage of certain embodiments is that at least a portion of the implant is tapered, or conical, to fit snugly within the tapered sinus tarsi. Thus, the likelihood of localized pressure points between the implant and the surrounding bones, which may cause pain or even result in the insert popping out of the sinus tarsi, is reduced as compared with prior implants. In addition, the insert may include threads that are sharp enough to help hold the insert in place within the person's sinus tarsi, yet dull enough to reduce the likelihood of the threads causing pain to the person as compared with prior implants. For example, in certain embodiments, the width of the crest of each thread may be wide enough to reduce or eliminate the likelihood of the threads causing pain.

Yet another advantage is that in certain embodiments, the implant includes one or more slots that increase the elasticity and resiliency of the implant. Thus, the implant may be better able to dissipate forces caused by impacts experienced by the implant, such as impacts caused by the person walking or running, for example.

Certain embodiments may provide all, some, or none of these advantages. Certain embodiments may provide one or more other advantages, one or more of which may be apparent to those skilled in the art from the figures, descriptions, and claims included herein.

BRIEF DESCRIPTION OF THE DRAWINGS

To provide a more complete understanding of the present invention and the features and advantages thereof, reference is made to the following description taken in conjunction with the accompanying drawings, in which:

FIGURES 1A-1C illustrate a subtalar implant in accordance with one embodiment of the present invention;

FIGURE 2 illustrates a detail of an example slug used to form the implant shown in FIGURES 1A-1C; and

FIGURES 3A-3C illustrate various subtalar implants according to other embodiments of the present invention.

DESCRIPTION OF EXAMPLE EMBODIMENTS

According to the present invention, a conical, threaded medical implant is adapted for implantation within a person's body to limit motion in a joint having excessive mobility. In certain embodiments, the medical implant is a subtalar implant adapted for implantation into the person's body and sized to fit within a sinus tarsi of a subtalar joint in the person's body for at least partially preventing displacement of the talus. However, it should be understood that various implants discussed herein may be otherwise used without departing from the scope of the invention.

FIGURES 1A-1C illustrate a subtalar implant 10 in accordance with one embodiment of the present invention. In particular, FIGURE 1A illustrates an external side view of implant 10, FIGURE 1B illustrates a cross-sectional view of implant 10 taken along line A-A of FIGURE 1A, and FIGURE 1C illustrates an external end view of implant 10. In general, subtalar implant 10 may be inserted into the sinus tarsi of a person suffering from pes valgo planus in a subtalar arthroereisis operation. Once inserted, implant 10 may reduce calcaneal eversion and block excessive displacement of the talus, thus correcting the person's pes valgo planus. In addition, implant 10 may allow normal motion of the subtalar joint while correcting the pes valgo planus, thus allowing the person to function normally.

As shown in FIGURE 1A, subtalar implant 10 includes a substantially conical body 12, a plurality of threads 14, and an engagement 16. Threads 14 are formed around the exterior surface 18 of body 12 and extend from a leading end 20 to a trailing end 22 of body 12. Threads 14 are provided to guide the insertion of implant 10 into, and to help secure implant 10 within, the sinus tarsi of a person. Each thread 14 includes a leading flank 24, a trailing flank 26, and a crest 28 connecting leading flank 24 with trailing flank 26. A root 30 is formed between each pair of adjacent threads 14 and connects the leading end 20 of one thread with the trailing end 22 of an adjacent thread 14.

As shown in FIGURE 1B, engagement 16 is formed in trailing end 22 of body 12 and is coaxial with a bore 32 extending from leading end 22 of body 12 to engagement 16. Engagement 16 is adapted to receive and be engaged by an

implantation tool such that implant 10 may be rotated about a longitudinal axis 34 for the implantation of implant 10 into the sinus tarsi. In this embodiment, engagement 16 comprises a recess having a hexagonal portion 36 integrated with a cylindrical portion 38 such that engagement 16 is adapted to receive and be engaged by a hex-head implantation tool, for example. In other embodiments, engagement 16 may comprise any other suitable types of recesses or other engagements adapted to receive or mate with other implantation tools. For example, engagement 16 may comprise a recess having a cruciform, rectangular, octagonal, or other shape.

FIGURE 1B also illustrates various dimensions that define the shape of implant 10. For example, body 12 is at least partially defined by a length 40, a leading end diameter 42, and a taper angle 44. Threads 14 are at least partially defined by a thread angle 50, a pitch 52, a thread height 54, a root width 56, and a crest width 58. A variety of implants 10 may be formed in various sizes and having various values for the dimensions listed above. For example, length 40, leading end diameter 42, and taper angle 44 may be appropriately sized to fit within the sinus tarsi of a person. Since the sinus tarsi of different people may have a range of sizes, a variety of implants 10 may be provided having a range of lengths 40, leading end diameters 42, and taper angles 44 such that an appropriate implant 10 may be selected for each person based on the size and shape of that person's sinus tarsi. For example, for various implants 10, length 40 may range from approximately 0.39 inches to approximately 0.78 inches and leading end diameter 42 may range from approximately 0.078 inches to approximately 0.39 inches. In the embodiment shown in FIGURES 1A-1C, length 40 is approximately 0.59 inches and leading end diameter 42 is approximately 0.163 inches.

Similarly, a range of taper angles 44 may be used in various implants 10 to correspond with a range of taper angles of the sinus tarsi of various people. For example, in a variety of implants 10, taper angle 44 may range from 10 to 30 degrees. In certain embodiments, taper angle 44 may range from approximately 15 to 20 degrees. In the embodiment shown in FIGURES 1A-1C, taper angle 44 is approximately 18 degrees. By providing implants 10 having a range of taper angles

44, an implant 10 may be selected for a particular person that has a taper angle 44 substantially equal to the taper of the sinus tarsi of that person. Thus, implant 10 may fit more precisely or snugly within the tapered sinus tarsi as compared with prior cylindrical or other non-tapered implants. As a result, the likelihood of pressure points between implant 10 and the surrounding bones (including the talus and the calcaneus) which may cause pain or even result in insert 10 popping out of the sinus tarsi, is reduced as compared with prior cylindrical or other non-tapered implants.

The dimensions defining threads 14 may be selected based on a number of objectives, such as to provide implant 10 that may be easily threaded into the sinus tarsi and adequately secured in place within the sinus tarsi, and to limit or avoid pain to the patient, for example. In certain embodiments, threads 14 may be formed such that they are sharp enough to adequately secure implant 10 in place within a person's sinus tarsi, yet not sharp enough to cause pain to the person. In particular, the ratio of crest width 58 to one or more other thread dimensions, such as pitch 52 or thread height 54 for example, may be selected in order to provide these objectives. For example, the ratio of crest width 58 to pitch 52 may be greater than or approximately equal to 0.15. In certain embodiments, the ratio of crest width 58 to pitch 52 is between approximately 0.2 and 0.4. In the embodiment shown in FIGURES 1A-1C, the ratio of crest width 58 to pitch 52 is approximately 0.25. As another example, the ratio of crest width 58 to thread height 54 may be greater than or approximately equal to 0.3. In certain embodiments, the ratio of crest width 58 to thread height 54 is between approximately 0.5 and 1.0. In the embodiment shown in FIGURES 1A-1C, the ratio of crest width 58 to thread height 54 is approximately 0.72.

Other dimensions of threads 14 may similarly be selected based on various objectives of insert 10, such as those discussed above. For example, thread angle 50 may be between approximately 45 and 75 degrees. In the embodiment shown in FIGURES 1A-1C, thread angle 50 is approximately 60 degrees. As another example, pitch 52 may be between approximately 0.050 and 0.200 inches. In certain embodiments, pitch 52 is between approximately 0.080 and 0.120 inches. In the embodiment shown in FIGURES 1A-1C, pitch 52 is approximately 0.090 inches. In

certain other embodiments, pitch 52 is approximately 0.100 inches. As yet another example, thread height 54 may be between approximately 0.010 and 0.060 inches. In certain embodiments, thread height 54 is between approximately 0.020 and 0.050 inches. In the embodiment shown in FIGURES 1A-1C, thread height 54 is approximately 0.032 inches. In certain other embodiments, thread height 54 is approximately 0.041 inches. As yet another example, root width 56 may be between approximately 0.020 and 0.040 inches. In the embodiment shown in FIGURES 1A-1C, root width 56 is approximately 0.030 inches.

Taken together, FIGURES 1B and 1C illustrate engagement 16 and bore 32 formed in body 12 of implant 10. Bore 32 is at least partially defined by a bore diameter 60. Hexagonal portion 36 of engagement 16 is defined by a width 62 and depth 64 and cylindrical portion 38 engagement 16 is defined by a diameter 66 and depth 68. In the embodiment shown in FIGURES 1A-1C, hexagonal portion 36 has a width 62 and depth 64 of approximately 0.159 inches and 0.15 inches, respectively, while cylindrical portion 38 has a diameter 66 and depth 68 of approximately 0.166 inches and 0.20 inches, respectively. As shown in FIGURE 1C, bore 32 has a diameter between 0.067 and 0.072 inches.

Implant 10 may be formed from any one or more materials suitable for forming medical implants, such as materials that have high strength-to-weight ratios and that are inert to human body fluids. In certain embodiments, implant 10 is formed from one or more titanium alloys, which provide several benefits. For example, titanium alloys are relatively lightweight, provide adequate strength for withstanding forces typically experienced by an implanted medical implant, are inert to human body fluids, and are visible in radiographs of the implant region. In particular embodiment, implant 10 is formed from the titanium based alloy Ti6Al4V ELI (per ASTM F136), which provides a desirable combination of benefits, such as those discussed above. In certain other embodiments, implant 10 is formed from one or more resorbable polymers, such as polylactides, polyglycolide, glycolide/lactide copolymers or other copolymers for example, or one or more implantable plastics, such as polyethylene or acetal copolymers for example.

FIGURE 2 illustrates a detail of a slug 80 used to form implant 10 according to one embodiment of the present invention. In particular, threads 14 are formed in slug 80 to form implant 10 shown in FIGURES 1A-1C. As shown in FIGURE 1, slug 80 includes a conical portion 82 and a cylindrical portion 84. Cylindrical portion 84 may be provided for the machining of implant 10. For example, cylindrical portion 84 of slug 80 may be gripped by various machining tools during the machining of slug 80 to form implant 10.

Slug 80 is at least partially defined by a taper angle 86, a leading end diameter 88, a cylindrical portion diameter 90, a cylindrical portion length 92, and an overall length 94. In the embodiment shown in FIGURE 2 that is used to form implant 10 shown in FIGURES 1A-1C, taper angle 86 is approximately 18 degrees, leading end diameter 88 is approximately 0.163 inches, cylindrical portion diameter 90 is approximately 0.315 inches, cylindrical portion length 92 is approximately 0.110 inches, and overall length 94 is approximately 0.59 inches.

FIGURES 3A-3C illustrate various subtalar implants according to other embodiments of the present invention. As shown in FIGURE 3A, implant 100 includes a leading conical portion 102, a trailing conical portion 104, and a cylindrical portion 106 connecting leading conical portion 102 with trailing conical portion 104. Cylindrical portion 106 may be used to hold implant 100 during the machining of implant 100. Implant 100 also includes a slot 108 extending across the diameter of trailing conical portion 104 and extending from a trailing end 110 of implant 100 substantially or completely through the length of trailing conical portion 104. Slot 108 may provide increased elasticity and resiliency to implant 100, which may reduce the likelihood of structural failure of implant 100 when subjected to various forces and stresses associated with being implanted in a person's sinus tarsi. For example, slots 108 may dissipate a portion of various impact forces experienced by implant 100, such as impact forces caused by the person walking or running.

As shown in FIGURE 3B, implant 120 includes a leading conical portion 122, a trailing conical portion 124, a cylindrical portion 126 connecting leading conical portion 122 with trailing conical portion 124, and a slot 128. However, unlike slot

108 of implant 100, slot 128 of implant 120 extends across the diameter of leading conical portion 122 and extends from a leading end 130 of implant 120 substantially or completely through the length of leading conical portion 122. As discussed above regarding slot 108 of implant 100, slot 128 of implant 120 may provide increased elasticity to implant 120, which may reduce the likelihood of structural failure of implant 120 when subjected to various forces and stresses associated with being implanted in a person's sinus tarsi.

As shown in FIGURE 3C, implant 140 includes a leading conical portion 142, a trailing conical portion 144, a cylindrical portion 146 connecting leading conical portion 142 with trailing conical portion 144, a first slot 148, and a second slot 150. First slot 148 extends across the diameter of leading conical portion 142 and extends from a leading end 152 of implant 140 substantially or completely through the length of leading conical portion 142. Second slot 150 extends across the diameter of trailing conical portion 144 and extends from a trailing end 154 of implant 140 substantially or completely through the length of trailing conical portion 144. In the embodiment shown in FIGURE 3C, first slot 148 and second slot 150 are formed substantially perpendicular to one another. As discussed above regarding slots 108 and 128, slots 148 and 150 of implant 140 may provide increased elasticity to implant 140, which may reduce the likelihood of structural failure of implant 140 when subjected to various forces and stresses associated with being implanted in a person's sinus tarsi.

Although the present invention has been described with several embodiments, a number of changes, substitutions, variations, alterations, and modifications may be suggested to one skilled in the art, and it is intended that the invention encompass all such changes, substitutions, variations, alterations, and modifications as fall within the spirit and scope of the appended claims.